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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,624	04/09/2004	Michael John Dunkley	0197.00	8935

21968 7590 10/16/2007
NEKTAR THERAPEUTICS
201 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3771

MAIL DATE	DELIVERY MODE
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10/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/821,624

Applicant(s)

DUNKLEY ET AL.

Examiner

Shumaya B. Ali

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-34 is/are pending in the application.
- 4a) Of the above claim(s) 13, and 21-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15-20, 27-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

In response to the office action mailed on 1/26/07, Applicant has amended claims 1,29, and 33, and cancelled claim 14. Claims 13, and 21-26 were previously withdrawn. Currently, claims 1-13, and 15-34 are pending in the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 20,27, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Valentini et al. US 4,069,819.

As to claim 20, Valentini discloses an aerosolization apparatus (fig.2) comprising a housing defining a chamber (B) having one or more air inlets (H), the chamber being sized to receive a capsule (C) which contains an aerosolizable pharmaceutical formulation (col.1 line 49); a puncturing mechanism (fig.3, E) within the housing, the puncturing mechanism comprising an alignment guide (L) and a puncture member (D), wherein the alignment guide comprises a surface (see labeled fig.3 attached below) adapted to contact the capsule while the puncture member is advanced into the capsule to create an opening in the capsule (col.2 lines 65-68, col.3 lines 1-10), and wherein the surface comprises one or more protrusions (see labeled fig.3, attachment below) for contacting the capsule, and an end (A) section associated with the housing,

Art Unit: 3771

the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule (col.3 lines 10-16).

As to claim 27, Valentini discloses wherein surface comprises a passageway and wherein the puncture member slides within the passage (col.1 lines 46-49, col.2 lines 46-54).

As to claim 28, Valentini discloses wherein the inlet is shaped to crease a swirling airflow within the chamber (col.3 lines 11-16).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12,15-19, and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentini et al. US 4,069,819 in view of Citterio US 2003/0000523 A1.

As to claim 1, Valentini discloses an aerosolization apparatus (see fig.2) comprising: a housing defining a chamber (B) having one or more air inlets (H), the chamber being sized to receive a capsule (C) which contains an aerosolizable pharmaceutical formulation (col.1 line 49); a puncturing mechanism (fig.3, M-T) within the housing, the puncturing mechanism comprising an alignment guide (L) and a puncture member (D), wherein the alignment guide comprises a surface (see labeled fig.3, attachment below) adapted to contact the capsule while the puncture member is advanced into the capsule to create an opening (col.2 lines 65-68, col.3 lines 1-10) in the capsule, and wherein at least a portion of the surface is sloped at an angle which is less than 55 degrees relative to the longitudinal axis of the capsule (see labeled fig.3); and an end section (A) sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to inhale aerosolized pharmaceutical formulation that has exited the capsule through the opening created in the capsule (col.3 lines 10-16). Valentini however lacks the end section is removably connected to the housing and wherein the end section may be removed from the housing to provide access to the chamber. However, Citterio (in figures 1-6) teaches an end section (3) of an aerosolization apparatus that is removably connected (by disengaging 5 and 8 from 2, see paragraphs 17-20) to a housing (2); Citterio further teaches the end section may be removed from the housing to provide access to the chamber (see fig.1 and paragraph 26). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Valentini in order to provide an end section that is removably connected to the housing because it is known in the art as taught by Citterio.

As to claim 2, Valentini discloses wherein the surface is sloped at an angle, which is from 35 to 55 degrees relative to the longitudinal axis of the capsule (see labeled fig.3).

As to claim 3, Valentini discloses wherein the surface is sloped at an angle, which is from 37 to 50 degrees relative to the longitudinal axis of the capsule (see labeled fig.3).

As to claim 4, Valentini discloses wherein the surface is sloped at an angle of about 45 degrees relative to the longitudinal axis of the capsule (see labeled fig.3).

As to claim 5, Valentini discloses wherein the puncturing mechanism is at least partially within the chamber (see fig.2).

As to claim 6, Valentini discloses wherein surface comprises a passageway (fig.2, H) and wherein the puncture member slides (col.1, lines 16-49, col.2 lines 30-37) within the passageway.

As to claim 7, Valentini discloses wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the longitudinal axis of the puncture member (see labeled fig.3).

As to claim 8, Valentini discloses wherein the surface is sloped at an angle which less than 55 degrees relative to the longitudinal axis of the chamber_(see labeled fig.3).

As to claim 9, Valentini discloses wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to an inhalation direction (see labeled fig.3).

As to claim 10, Valentini discloses wherein the surface is moveable (col.2 lines 65-68) within the chamber.

As to claim 11, Valentini discloses wherein the wherein the surface is sloped at an angle which less than 55 degrees relative to the direction of movement of the surface (see labeled fig.3).

As to claim 12, Valentini discloses wherein the surface comprises one or more protrusions and wherein the one or more protrusions (see labeled fig.3) are adapted to contact the capsule (col.2 lines 65-68).

As to claim 15, Valentini discloses wherein the puncture mechanism comprises a pair of puncture members (see fig.3, D).

As to claim 16, Valentini discloses wherein the puncture member is adapted to puncture only one end of the capsule (since puncture member is situated only one end of the device, it inherently punctures one end of the capsule).

As to claim 17, Valentini discloses wherein the chamber is elongated and wherein the capsule is received lengthwise within the elongated chamber (see fig.5).

As to claim 18, Valentini discloses wherein the width of the chamber is less than the length of the capsule (see fig.5).

As to claim 19, Valentini discloses wherein the inlet is shaped to create a swirling airflow within the chamber (col.3 lines 11-16).

As to claims 29-34, Valentini lacks a detailed description of the claimed steps, however discloses structural limitations required to perform the method steps (see above rejection cited for claims 1-13). Valentini however lacks inserting the capsule in a chamber defined by a body and a removable end portion. However, Citterio teaches removable end portion as applied to

claim 1. Thus, the method steps as cited in claims 29 and 30 would have been obvious result of using the apparatus of Valentini as modified by Citterio.

Response to Arguments

Applicant's arguments filed on 7/26/07 with respect to claims 20,27, and 28 have been fully considered but they are not persuasive. On page 7, lines 21-24 Applicant argues that Valentini lacks "one or more protrusions", however, such protrusions are clearly depicted in figure 3 (see also labeled fig.3, attachment below). Thus, Valentini discloses the invention defined in claim 20. Thus, the rejection is maintained.

Applicant's arguments with respect to claims 1-12,15-19, and 29-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

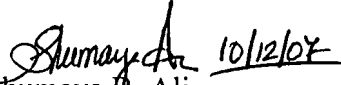
Art Unit: 3771


however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Shumaya B. Ali
Examiner
Art Unit 3771


JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
10/12/07

